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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/032,256 | 12/21/2001 | Lewis A. Chodosh | 22253-70421 | 6641 |

7590 07/15/2004
DILWORTH PAXSON LLP
1735 Market Street
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EXAMINER

FETTEROLF, BRANDON J

| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED: 07/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|---------------------------------------|--|
| Office Action Summary | Application No. 10/032,256 | Applicant(s) CHODOSH ET AL. | |
| | Examiner Brandon J Fetterolf, PhD | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, as specifically drawn to a purified cancer-linked protein kinase, Hunk, comprising the amino acid sequence set for in SEQ ID NO: 2, classified in class 530, subclass 350.
- II. Claims 3-4, 39-40, 42-44 and 46, as specifically drawn to an isolated nucleotide comprising the nucleotide sequence set for in SEQ ID NO: 1, classified in class 536, subclass 23.1.
- III. Claims 5, 7, 9, 17, and 21, as specifically drawn to a method of delivering the protein of SEQ ID NO: 2 to a target cell for the treatment of cancer, classified in class 424, subclass 184.1.
- IV. Claims 6, 8, 16, and 20, as specifically drawn to a method of delivering the nucleotide of SEQ ID NO: 1 to a target cell for the treatment of cancer, classified in class 514, subclass 44.
- V. Claims 10, 12, and 18, as specifically drawn to a method of delivering an inhibitor of the protein of SEQ ID NO: 2 to a target cell for the treatment of cancer, classified in class 424, subclass 184.1.
- VI. Claims 11 and 19, as specifically drawn to a method of delivering an inhibitor of the isolated nucleic acid of SEQ ID NO: 1 wherein said inhibitor is antisense to a target cell for the treatment of cancer, classified in class 514, subclass 1.

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- VII. Claims 13, 15, 22, 24, as specifically drawn to a method of delivering an enhancer of the protein of SEQ ID NO: 2 to a cell for the treatment of cancer, classified in class 424, subclass 184.1.
- VIII. Claims 14, 23, 25, as specifically drawn to a method of delivering an enhancer of the isolated nucleotide of SEQ ID NO: 1 to a cell for the treatment of cancer, classified in class 514, subclass 1.
- IX. Claims 26-29, as specifically drawn to a method of diagnosing a disease by detecting or measuring the overexpression of the protein of SEQ ID NO: 2 in a target cell, classified in class 436, subclass 64; class 435, subclass 6.
- X. Claims 26, 30-31, as specifically drawn to a method of diagnosing a disease by detecting or measuring the underexpression of the protein of SEQ ID NO: 2 in a target cell, classified in class 436, subclass 64; class 435, subclass 6.
- XI. Claims 32-38, as specifically drawn to a method of rapid screening for a selected compound that modulates the activity of a HUNK kinase, classified in class 435, subclass 4.
- XII. Claim 41, as specifically drawn to an antibody specific for the polypeptide of SEQ ID NO: 2, classified in class 530, subclass 387.7.
- XIII. Claim 45 and 47, as specifically drawn to a transgenic animal comprising a transgene comprising the isolated nucleic acid of SEQ ID NO: 1, classified in class 800, subclass 8.

The inventions are distinct, each from the other because of the following reasons:

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The inventions of Groups I-II and XII-XIII represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. For example, Group I is drawn specifically to a purified cancer-linked protein kinase, Hunk, comprising the amino acid sequence set forth in SEQ ID NO: 2, whereas Group II is drawn to an isolated nucleotide comprising the nucleotide sequence set forth in SEQ ID NO: 1.

The invention of Groups III-XI are materially distinct methods of which differ at least in objectives, method steps, reagents and/or dosage and/or schedules used, response variables, and criteria for success. For example, Group III is drawn to a method of delivering a protein to a target cell, whereas Group XI is drawn to a method of rapid screening for compounds that modulate the activity of HUNK.

The invention of Group I and the methods of Groups III, IX, X, and XI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the protein product as claimed can be used in a materially different process such as used to treat a disease or as a diagnostic tool.

The inventions of Group II and the method Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the isolated nucleic acid as claimed can be used in a materially different process such as used for the production of a protein or in nucleic acid hybridization assays.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination

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purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search of the literature required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Note:

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF



GARY B. NICKOL, PH.D.
PRIMARY EXAMINER